

Review Article

Scoping review of peer reviewed publications addressing rehabilitation for people sustaining traumatic spinal cord injury

Lynn H. Gerber^{1,2}, Haley Bush ¹, Xinsheng “Cindy” Cai³, Leslie Morse ⁴,
Lynn Worobey ⁵, Steven Garfinkel³

¹Betty and Guy Beatty Center for Integrated Research, Inova Health System, Falls Church, Virginia, USA, ²Center for the Study of Chronic Illness and Disability, George Mason University, Fairfax, Virginia, USA, ³American Institute for Research, Washington, DC, USA, ⁴Craig Center for Regenerative Research, University of Colorado, Englewood, Colorado, USA, ⁵Department of Physical Medicine & Rehabilitation, University of Pittsburgh, Pittsburgh, Pennsylvania, USA

Study Design: Scoping review

Objective: To study the design, clinical setting and outcome measures used in spinal cord injury rehabilitation publications.

Methods: A literature search on PubMed and Medline was conducted focusing on articles published between 1990–2016 and using “traumatic SCI”, “functional outcomes”, “rehabilitation”, “work” and “return to work” as outcomes. Studies were categorized based on design (intervention, including RCTs vs. non-intervention studies), settings (inpatient vs. outpatient vs. transition), and outcome measures used (impairment vs. function vs. participation/integration vs. quality of life vs. symptoms). Work-related studies were categorized independently.

Results: Five hundred forty-four articles met the inclusion criteria. Of these, 234 were interventional studies, including 23 RCTs. Studies were evenly divided among inpatient, outpatient and transition settings. Of the 234 interventional studies, 143 used functional evaluations. Sixty-one different functional instruments were used, with a predominant use of the Functional Independence Measure (61 times) and an additional use of SCI-specific measures, i.e. Spinal Cord Independence Measure and Craig Handicap Assessment and Reporting Technique (13 times each). Fifty-one studies measured mobility, while only three measured hand functions. The work-related sub-analysis revealed 32 intervention studies (no RCTs), of which 15 used functional evaluations and only three focused on tetraplegia.

Conclusion: Our study revealed a paucity of intervention trials and RCTs, indicating a dearth of knowledge that would be needed to establish evidence-based practice guidelines. This is particularly true for tetraplegia. While standard measures of function were frequently used, providing valuable data, there is no consensus about what exact outcome measure to use. Using newer measurement techniques, for instance based on the application of item response theory, should be considered to enhance uniformity.

Keywords: Function, Rehabilitation, Scoping review, Spinal cord injury

Context

Physical Medicine and Rehabilitation (PMR) is a medical specialty that aims to improve functional

outcomes. The World Health Organization (WHO) defines health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”.¹ Functional outcomes measure whether individuals return to needed and desirable routines/roles including self-care, work, school and social activities. The International Classification of Functioning, Disability and Health (ICF)² was used to establish outcome domains. Functioning was defined as the “dynamic interaction between a person’s health

Correspondence to: Lynn H. Gerber, Department of Medicine, Inova Fairfax Medical Campus, 3300 Gallows Road, Falls Church, VA 22042, USA; Ph: 703-776-4027; George Mason University, 4400 University Drive, Fairfax, VA 22030, USA. Email: ngerber1@gmu.edu
Supplemental data for this article can be accessed at <https://doi.org/10.1080/10790268.2019.1645415>.

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conditions, environmental factors, and personal factors. It is a composite of multiple domains that, when taken collectively, represent human social, cognitive and social activities".² By comparison, impairment is "any loss or abnormality of psychological, physiologic, or anatomic structure or function".¹ Function has been identified as an important measure of health³⁻⁵ and addressing functional improvement is necessary if clinical rehabilitation research (CRR) is to provide relevant contributions that meet patients' needs.

The scoping review reported here does not attempt to attribute quality or level of evidence to the identified studies, but rather to assess the information these studies convey that addresses the ICF domains pertaining to function, participation and activity congruent with patients' expectations and compatible with patients' needs and desires.⁶ Research results addressing these are likely to be used in practice⁷ as long as the quality of research is good. Therefore, the aims of this scoping review were to review CRR publications pertaining to traumatic Spinal Cord Injury (SCI) and determine whether the research performed intervention trials and used function as an outcome.

Methods

A scoping review is broad based and structured to enable the reviewers to determine whether the subject of interest is addressed in the current literature.⁸ We used Arksey and O'Malley scoping review methodology following the general 5 steps: 1. Identify the question; 2. Identify relevant studies; 3. Develop predetermined search terms that are refined over time into inclusion/exclusion criteria; 4. Chart the data; 5. Collate and report findings. According to this methodology, the following question was identified: Do clinical rehabilitation research (CRR) publications report interventions trials, include functional outcomes as endpoints and get conducted in variety of clinical and community settings? We used the following approach to identify relevant studies: The review protocol was prepared, reviewed, and revised by an advisory board consisting of members of the National Institutes of Disability, Independent Living and Rehabilitation Research (NIDILRR) Model Systems (MS) SCI Program (LM, LW).⁹ We conducted PubMed and Medline searches from 1990–2016 databases using the following predetermined search terms: "traumatic SCI" and "functional outcomes" and "rehabilitation". It was determined that these search terms did not result in studies that reported "work" or "return to work", which the authors believed would be important to identify. Hence, a separate search was conducted using the

following terms: "traumatic SCI" and "rehabilitation" and "work" or "return to work". Two coders (HB, LG) conducted the article reviews. (Fig. 1) Reasons for article exclusion included non-human research, outside the designated time frame, and non-rehabilitation research. We employed both the WHO and ICF definitions for the following terms: rehabilitation, impairment, function, and activity, participation/integration.¹⁰ Articles were separated into interventional and non-interventional studies. We also identified studies that were randomized controlled trials. Analyses were performed on rehabilitation intervention studies. Among the intervention studies, we established two groups: a group called the standard evaluation group and the impairment only group. To be assigned to the standard evaluation group, the outcomes of the intervention had to include a measure of function, participation or return to work. The study also included measures of impairments and symptoms. Measures of behavior, mood and cognition were classified as symptoms and not function. Lastly, participation and integration were defined as "involvement of people in all areas of life, and the participation restriction they experience (functioning of a person as a member of society)".¹⁰

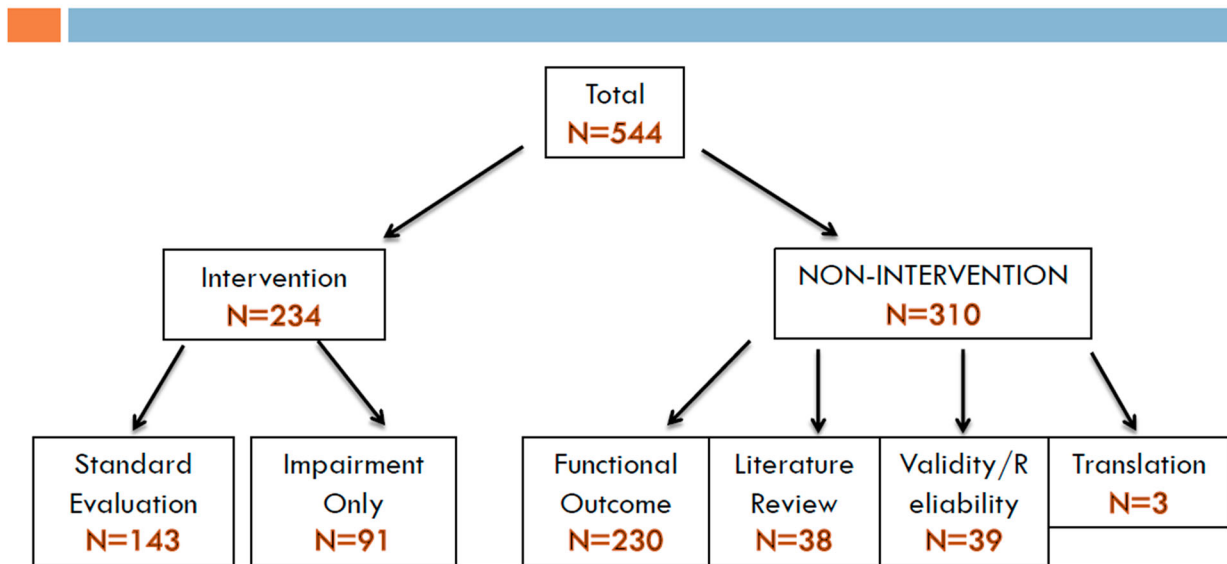
The reviewers conducted a count of the studies that were interventions and those that were not and a count of the studies that included functional measures and the specific measures that were used. Next, articles were totaled for the studies performed in outpatient, inpatient or inpatient to outpatient settings. A tally of the distribution of outcome domains was determined with column headings chosen as described by the ICF. When the publication included a quality of life (QoL) measure, it was noted. Symptom measures were listed separately. Instruments that measured more than one domain were scored for both. Impairment only, symptom only or QoL only measures, were not scored as measures of function.

Results

Intervention vs non-interventions studies

Five hundred and forty-four articles met inclusion criteria for the study, of which 234 were interventional studies. One hundred and three used at least one functional outcome measure (Fig. 1). There were 75 work related outcome studies, 32 were intervention studies and 15 measured a functional outcome. (Fig. 2). The distribution of outcome measures used in the intervention studies is tabulated in Fig. 1. CRR publications have steadily risen over the past 25 years, along with PubMed and Medline publications. There has been a

SCI Article Breakdown



Count	Instrument Name	Impairment	Function	Societal Integration	Quality of Life	Symptoms	% of Total
1	10 Minute Walk Test		X				<1
34	100m, 10m time walked		X				10
34	6 Minute Walk Test		X				10
1	9 minute walking test		X				<1
2	Activities-Specific Balance Confidence Scale		X				<1
33	American Spinal Injury Association Impairment Scale	X					9
4	Ashworth Scale	X					1
1	Australian National Sub-Acute and Non-Acute (AN-SNAP)	X	X				<1
8	Barthel Index		X				2
2	Barthel Index Modified		X				<1
20	Berg Balance Scale (BBS)	X	X				6
1	Borg CR10					X	<1
2	Canadian Occupational Performance Measure (COPM)		X	X	X		<1
1	Complete Minnesota Dexterity Tests	X					<1
1	Coping Inventory for Stressful Situation (CISS)					X	<1
12	Craig Handicap Assessment and Reporting Technique (CHART)		X	X			3
1	Craig Handicap Assessment and Reporting Technique-SF (CHART-SF)		X	X			<1
2	Dynamic Gait Index		X				<1
2	Emory Functional Ambulation Profile		X				<1
1	Five times Sit-to-Stand Test (FTSST)		X				<1
1	Functional Ambulation Category Scale (FAC)	X	X				<1
61	Functional Independence Measures	X	X				17
2	Functional Reach Test		X				<1
1	Glasgow Outcome Scale	X					<1
3	Grasp and Release Test (GRT)	X					<1
3	Hospital Anxiety and Depression Scale (HADS)					X	<1
1	International Association of Neurorestoratology Spinal Cord Injury Functional Rating Scale (IANR-SCI-FRS)		X			X	<1
1	Jebsen-Taylor Hand Function Test		X				<1
1	Lateral Functional Reach Test (LFRT)	X					<1
1	Locomotion and Neuropathic Painscale					X	<1
10	Lower Extremity Motor Scores (LEMS)	X					3
3	Manual Muscle Test (MMT)	X					<1
1	Modified Rankin Scale		X				<1
1	Needs Assessment Checklist (NAC)		X	X		X	<1
1	Neuromuscular Recovery Scale		X				<1
1	Northwick Park Dependence Score (NPDS)		X				<1
4	Patient Health Questionnaire-9					X	1
1	Peds QL		X	X			<1
1	Personality Assessment Inventory					X	<1
1	Purdue Pegboard	X					<1
3	Quadriplegia Index of Function		X				<1
1	Rehabilitation Complexity Scale (RCS)	X	X				<1
1	Rehabilitation Engineering Laboratory Hand Function Test	X					<1
1	Reintegration to Normal Living Index			X	X		<1
3	Rivermead Mobility Index		X				<1
6	Satisfaction with Life Survey (SWLS)					X	2
1	Schedule for the Evaluation of Individual QoL Direct Weighing					X	<1
1	Segway Task Assessment		X				<1
1	Sensory Level Test	X					<1
3	Short Form-36		X	X		X	<1
10	Spinal Cord Independence Measure (SCIM) I		X				3
3	Spinal Cord Independence Measure (SCIM) II		X				<1
4	Spinal Cord Injury Functional Ambulation Profile (SCI-FAP)		X				1
22	Time up and Go (TUG)		X				6
2	Toronto Rehabilitation Institute Hand Function Test (TRI-HFT)	X					<1
1	Upper Extremity Capabilities Questionnaire	X					<1
1	Van Lieshout Hand Function Test	X					<1
1	Veterans RAND 36-item health survey		X	X		X	<1
1	Visual Analog Scale for Pain	X					<1
8	Walking Index for Spinal Cord Injury (WISCI-I)		X				2
13	Walking Index for Spinal Cord Injury (WISCI-II)		X				4

Figure 1 Representation of article selection and categorization and process.

SCI Work Sub-Analysis Article Breakdown

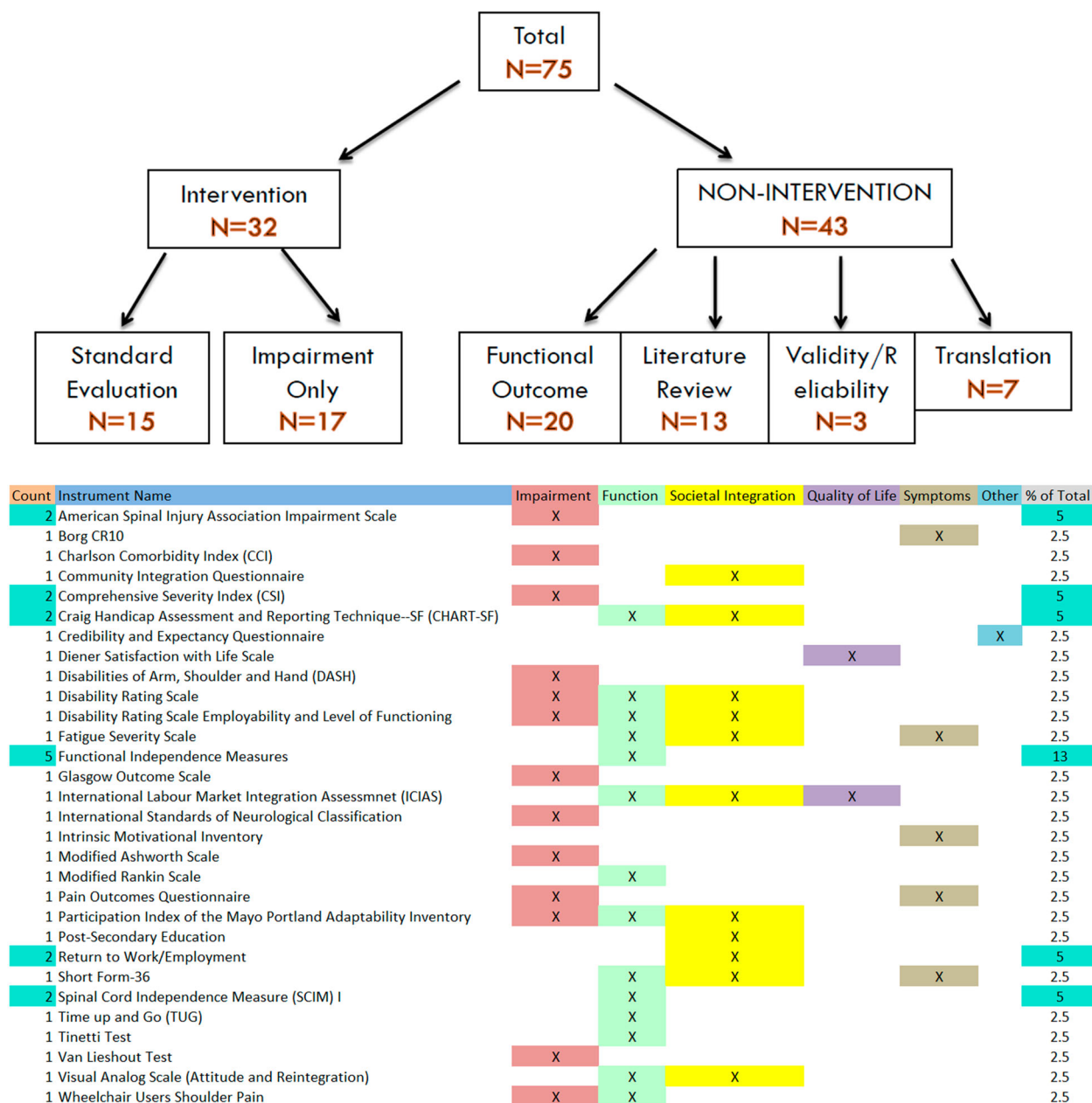


Figure 2 Representation of article selection and categorization and process for work sub-analysis articles.

modest rise in intervention trials and RCT's. (Fig. 3). Appendix A provides the publications reviewed, and a brief synopsis in both the general and work-related publications searched.

Study setting

Thirty-five percent of the studies were performed in the inpatient setting, 35% in the outpatient setting and 30%

studied patients who transitioned from in to outpatient. We analyzed the proportion of intervention studies performed by MS health care providers ($n = 61$) compared with those not performed at an MS center ($n = 83$). Health care professionals working in the MS published 27 articles addressing transition from in to outpatient (43%) while non-MS investigators published 13/83 (15%).

Trends in the Number of Rehabilitation, SCI, and Randomized Controlled Trials in PubMed: 1990-2016

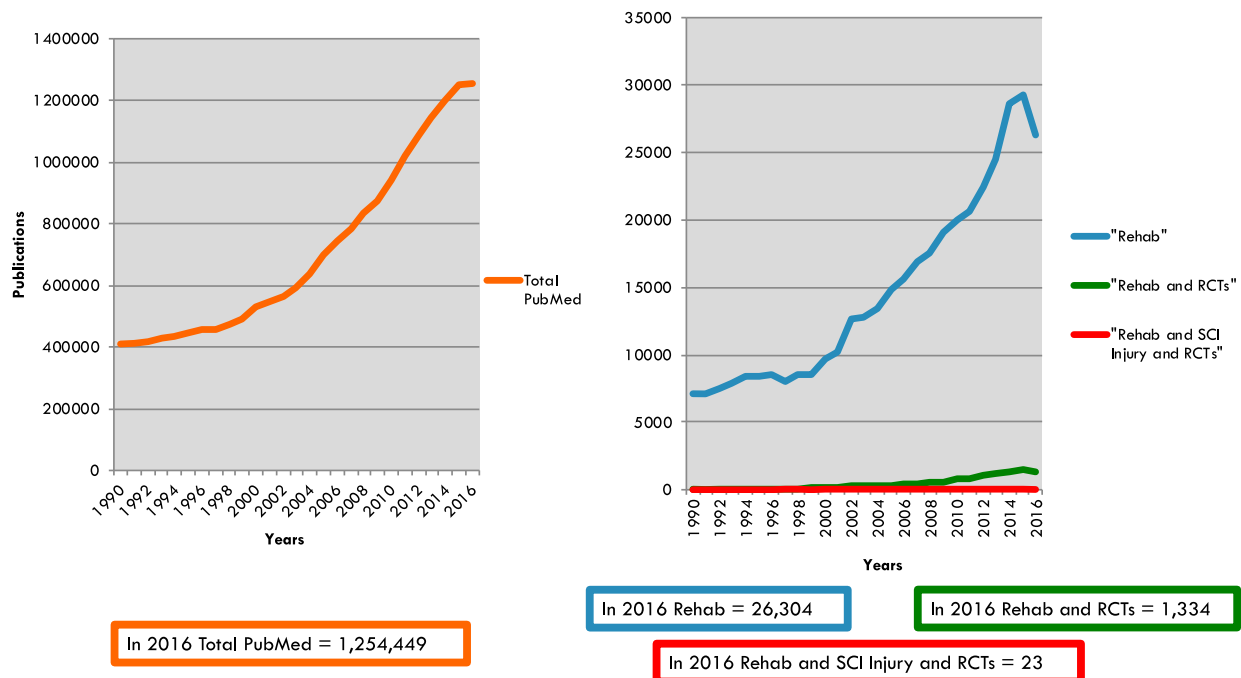


Figure 3 Trends in the number of rehabilitation, spinal cord injury and randomized controlled trials published in PubMed: 1990–2016.

Outcome measures

Sixty-one instruments were used (Fig. 1). Most of the instruments were used in combination. Symptoms were measured uniquely in 8 intervention trials. Quality of life measures were always used in tandem with societal integration measures. The 10 most frequently used are bolded. However, the great majority of measures fall into 3 groups. Measures of general function, of which the Functional Independence Measure (FIM) was used 61 times,^{11,12} followed by Spinal Cord Independence Measure (SCIM)¹³ and Craig Handicap Assessment and Reporting Technique (CHART)¹⁴ each of which were used 13 times. The utilization of FIM as an outcome measure has remained high over the past 5 years. Measures of ambulation such as the 6 and 9 min walk time, ($n = 35$), Timed Up and Go (TUG, $n = 22$).^{15,16}

Walking Index for spinal cord injury (WISCI I and II, $n = 21$)^{17,18} were included in 22% of the total standard evaluation articles. Wheeled mobility was infrequently used ($n = 7$). Very few measures of hand function were measured ($n = 3$). Only 15% in this review examined

individuals with cervical spinal cord injury. The distribution of types of measures used in the intervention trials are classified by their measurement domains including: 23 impairment measures, 42 measures of function, 13 measures of social integration and participation, 2 quality of life measures and 11 symptom measurement scales.

There were 39 different instruments used to assess work outcomes in the 15 standard evaluation group of articles. (Fig. 2) The top six most frequently used instruments account for 38.5% of all instruments used. The instruments used to examine work outcomes assessed multiple domains: 14 functional, 13 impairment, 10 societal integration measures. Three publications in this sub-analysis assessed persons with cervical spine injuries.

Discussion

This scoping review provides evidence that there has been a nearly fourfold increase in CRR publications between 1990–2016, with 1336 being RCTs for all rehabilitation publications and 23 of these for studies

pertaining to SCI. This is a very small number, only partially explained by the low prevalence of SCI (282,000) and incidence (17,000).¹⁹

Perhaps the most compelling issue is the low level of intervention studies and almost non-existent CRR for people with tetraplegia. While the number of RCTs has steadily risen over the past decade, the number must increase if clinical practice guidelines are to be developed. One possible approach to increasing the sample size for these studies is the use of shared data repositories and national networks, such as the Model Systems program in the United States.⁹ Another is the effort to establish credible metrics for effectiveness using newer approaches^{20,21} and modifications of Cochrane Reviews.^{22,23} If successful, this may generate quality data needed for guideline development.

Additionally, a challenge the field faces is the development of consensus about whether and which functional measures are to be used for clinical outcomes. The Centers for Medicare and Medicaid Services (CMS) accepted and now requires the use of functional outcome measures for determining response to treatment. The FIM has been the accepted assessment and has been used frequently as an outcome measure and predictor for functional independence. Changes in Medicare and Medicaid guidance has led to use of Continuity Assessment Recording and Evaluation Item Set (CARE), which may become the standard functional measure.

Significant conceptual questions persist in the SCI literature,²⁴ despite the clear improvement in taxonomy and methodology. Can impairment measures predict functional outcome? What role do symptoms play in functional activity? Some studies suggest that walking capacity is linked to function.^{25,26} Little data about linkage between symptoms/function exist.

This review suggests that although the FIM is the most frequently used functional measure, consensus on its use has not been reached. Further, since survivors of SCI are typically young adults, return to school, work readiness and employment are important to measure and are not measured by the FIM. Seventy-five publications addressed employment and only 32 were intervention trials.

Only 1/3 third of studies were performed in the outpatient setting and only MS investigators assessed transitions from inpatient to outpatient status in a substantial proportion of studies. In the authors' view, this type of research is needed and should be encouraged.

The ICF has provided a conceptual framework we used to classify domains for measuring outcomes and

was the basis for the assumption that to qualify as rehabilitation research, function is required and a desirable outcome. In this scoping review no intervention studies used impairment measures exclusively which is reassuring, even if there is no consensus about which measures should be used. Measures of participation, societal integration and personal/environmental influences for treatment and/or recovery are still not well represented in SCI research.

There remain gaps identified in this review: few studies report interventions, fewer include RCTs and almost none study tetraplegia; there is a lack of consensus on which outcome measures to use and which ICF measurement domains are necessary; few studies measure return to usual activities and roles and few investigators examine the transition period from hospital to community, important in the recovery cycle.

Conclusion

One of the limitations in this review is the approach the authors took in defining the inclusion/exclusion criteria. The requirement for studies to address function and/or functional limitation as an outcome of the research reduced the total number for inclusion. Additionally, the decision to exclude studies that measured only symptoms, certainly important to people's level of functioning, by themselves to do measure function. If they were the sole treatment outcome, they were deemed insufficient to establish functioning. Despite this limitation, this scoping review identified the design, clinical setting and outcome measures used in CRR and demonstrates gaps in the literature. These should be addressed because they are critical outcomes and are valued by patients with SCI and their rehabilitation health care teams.²⁶

Disclaimer statements

Contributors Development of Protocol was done by Lynn H. Gerber, Haley Bush, Xinsheng "Cindy" Cai, Leslie Morse, Lynn Worobey, Steven Garfinkel. Article Reviews and Selection were carried out by Haley Bush, Lynn H. Gerber. Analyses/interpretation were done by Lynn H. Gerber, Haley Bush, Xinsheng "Cindy" Cai, Leslie Morse, Lynn Worobey, Steven Garfinkel. Writing (Drafts and Final) was done by Lynn H. Gerber, Haley Bush, Xinsheng "Cindy" Cai, Leslie Morse, Lynn Worobey, Steven Garfinkel.

Funding Funded through a subcontract to George Mason University from the American Institutes

for Research, supported by Federal Grant (NIDILRR#90DP0012-01-00).

Conflicts of interest The authors have no conflict of interest to disclose. All authors read and approved the final version of the manuscript.

ORCID

Haley Bush  <http://orcid.org/0000-0003-0361-5150>

Leslie Morse  <http://orcid.org/0000-0002-7426-6341>

Lynn Worobey  <http://orcid.org/0000-0001-8795-6061>

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